Phase I trial: Parexel Code: PXL277433

| Submission date | Recruitment status | Prospectively registered |
|-------------------|----------------------|-----------------------------|
| 15/11/2023 | No longer recruiting | ☐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 16/11/2023 | Deferred | Results |
| Last Edited | Condition category | Individual participant data |
| 16/11/2023 | Other | Record updated in last year |

Plain English summary of protocol

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr David Steel

Contact details

Parexel Early Phase Clinical Unit (LONDON)
Northwick Park Hospital
Level 7
Watford Road
Harrow
London
United Kingdom
HA1 3UJ
+44 (0)7548098654
david.steel@parexel.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1007366

ClinicalTrials.gov number

Secondary identifying numbers

IRAS 1007366, Parexel PXL27743

Study information

Scientific Title

Phase I trial: Parexel Code: PXL277433 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives

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Ethics approval required

Ethics approval required

Ethics approval(s)

- 1. Approved 02/08/2023, Brent Research Ethics Committee Health Research Authority (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8128, +44 (0)207 104 8131; brent.rec@hra.nhs.uk), ref: 23/LO/0321; The HRA has approved deferral of publication of trial details.
- 2. Approved 17/08/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 29969/0159/001-0001; The HRA has approved deferral of publication of trial details

Study design

First-in-man safety, pharmacokinetics and pharmacodynamics trial in 88 healthy volunteers

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Safety

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacokinetic, Pharmacodynamic, Safety

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

15/05/2023

Completion date

30/08/2024

Eligibility

Key inclusion criteria

Healthy human volunteers

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Both

Target number of participants

88

Key exclusion criteria

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Date of first enrolment

22/08/2023

Date of final enrolment

30/08/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Parexel International; Parexel Early Phase Clinical Unit

Northwick Park Hospital Watford Road Harrow United Kingdom HA1 3UJ

Sponsor information

Organisation

Sanofi-Aventis Recherche & Développement

Sponsor details

1 avenue Pierre Brossolette Chilly-Mazarin France 91380

uk-medicalinformation@sanofi.com

Sponsor type

Industry

Website

https://www.sanofi.co.uk/en/contact

Funder(s)

Funder type

Industry

Funder Name

Sanofi-Aventis Recherche & Développement

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date

02/03/2027

Individual participant data (IPD) sharing plan

Qualified researchers may request access to patient-level data and related study documents including the clinical study report, study protocol with any amendments, blank case report form, statistical analysis plan, and dataset specifications. Patient-level data will be anonymized and study documents will be redacted to protect the privacy of trial participants. Further details on Sanofi's data sharing criteria, eligible studies, and process for requesting access can be found at: https://vivli.org

IPD sharing plan summary

Available on request